

K003889

JAN 24 2002

APPENDIX A. 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

A. Name, Address, Phone and Fax Number of the Applicant

Guidant EndoVascular Surgery Group
1525 O'Brien Drive
Menlo Park, CA 94025

Telephone: (650) 470-6200
Fax: (650) 470-6320

B. Contact Person

Jacqueline J. Jackson
Manager, Regulatory Affairs

C. Date Prepared

December 15, 2000

D. Device Name

Trade Name: ANCURE® Sheath
Classification Name: Catheter Introducer 21 CFR §870.1340 , Class II

E. Device Description

The ANCURE Sheath is an introducer sheath comprised of a sheath, an attached valve system, and a dilator. The tip of the dilator is tapered to facilitate atraumatic insertion of the sheath. The valve system of the ANCURE Sheath helps to maintain hemostasis during endovascular procedures. The outer surface of the sheath is hydrophilic coated to ease insertion and removal of the ANCURE Sheath. The ANCURE sheath has a 24.6 Fr inner diameter and a 27.9 Fr outer diameter. It will accommodate endovascular devices measuring up to 23.5 Fr.

F. Intended Use

The ANCURE Sheath designed to provide access to the vascular system. It is used for the insertion of vascular catheters through the iliac and femoral arteries into the aorta.

G. Substantial Equivalence

The ANCURE Sheath is substantially equivalent to the EVT (ANCURE) Expandable Sheath (510(k) K970470, Cleared July 31, 1997). The ANCURE Sheath is similar to the EVT (ANCURE) Expandable Sheath with respect to intended use, design, materials, and performance.

H. Device Safety & Performance Testing

The following tests were performed on the ANCURE Sheath:

1. Sheath tube to Adapter Joint
2. Guidewire Lumen Patency
3. Flush Port Air Flow
4. Flush Port Pull Test
5. Dilator Removal Test
6. Valve Actuation Test
7. Leak Test
8. Valve Clearance
9. Dilator Snap Force
10. Bending Strength of Sheath/Adapter Joint
11. Torsional Strength of Dilator Hub
12. Tensile Strength of Dilator Hub
13. Package seal integrity
14. Sterilization validation
15. Biocompatibility
16. Simulated Use Testing

The results of each test were found to be clinically acceptable.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 24 2002

Ms. Jacqueline J. Jackson
Manager, Regulatory Affairs
Guidant Endovascular Surgery Group
1525 O'Brian Drive
Menlo Park, CA 94025

Re: K003889
Trade Name: ANCURE® Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer.
Regulatory Class: II
Product Code: 74 DYB
Dated: January 4, 2002
Received: January 7, 2002

Dear Ms. Jackson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

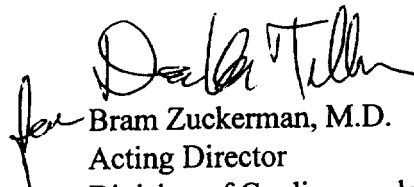
Page 2 - Ms. Jacqueline J. Jackson

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram Zuckerman".

Bram Zuckerman, M.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPENDIX B. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K003889


Device Name: ANCURE® Sheath

Indications for Use: The ANCURE® Sheath designed to provide access to the vascular system. It is used for the insertion of vascular catheters through the iliac and femoral arteries into the aorta.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒ OR Over-the-Counter Use ☐


Division of Cardiovascular & Respiratory Devices
510(k) Number K003889